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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,337	03/12/2004	Dean S. Irwin	PMEDEX.17CP1C	6234

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EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,337

Applicant(s)

IRWIN, DEAN S.

Examiner

Ahmed M. Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it exceeds the 150 words.

Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Chou U.S.

Patent No. 6,083,218

Chou discloses a method and apparatus for removing deceased tissue (dental caries), the apparatus comprising:

a source of UV light with the range of 300 and 315 nm (XeCl laser source generating 308 nm light (see Fig. 1; Col. 3, lines 34-41; and claim 1)); and a cooling subsystem for cooling the tissues at the target site (Col. 3, lines 1-2).

In this Office Action, it is noted that the applicant's instant claim is intended for the treatment of the skin tissue (soft tissue). It is further noted that the Chou patent is intended for the treatment of dental tissues (hard tissue). However, the type of tissue treated is an intended use and adds no structural and/or functional limitation to the claimed device. Furthermore, the device of Chou is fully capable for treating skin tissue (soft tissue). Therefore, Chou anticipates the claimed device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartman U.S. Patent No. 6,413,268 B1 in view of (Muller U.S. Patent No. 5,830,208.

Hartman discloses apparatus and method for targeted UV phototherapy of skin disorders such as psoriasis, vitiligo, eczema, and the like, as presently claimed (Col. 1, lines 6-1 1), the apparatus comprising:

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a source of high intensity UV light having an output energy in the wavelength range of 300 -315 nm (arc mercury lamp **12** of Hartman emits UVB light in the wavelength range between 300 -315 nm as presently claimed (see Col. 5. lines 22-24. and Col. 11. lines 22-27)) ;

a conduit (elongated light guide **16**) having an input end for receiving UV light from the source and an output end for emitting said UV light; and

a delivery device (handpiece **18**) attached to the output end of said conduit (see Figs. 1, 2 and 7).

As to the limitation "high intensity ultraviolet light equal to or greater than about 1 minimum erythema dose (MED) in the wavelength range of between about 300 and 315 nanometers" in claims 1 and 4 of the instant application, Hartman teaches that, initially, the MED for each patient is determined by irradiating series of small patches of skin (Col. 8, lines 19-24). He further teaches that the radiation dose delivered to the treatment area "may be up to six times the estimated MED for a patient" (Col. 11, lines 31-32). Hence, Hartman anticipates the claimed limitation.

However, although it is well known in the medical art to cool the skin during high-energy/intensity light therapy, Hartman fails to teach the use of a cooler or a cooling unit included in the delivery device for cooling the tissue. Nevertheless, to cool the skin tissue during phototherapy of the skin/tissue with high intensity/energy light is well known in the medical art.

Muller teaches a method and apparatus for treating dermatological conditions (such as skin pigmentation irregularities), the apparatus comprising; a radiation source

for providing treatment light in the visible and in the UV spectral range (see Fig. 4 and Col. 29-33); and cooling subsystems **20**, **160**, to provide cooling to the skin being treated (see Figs. 1 and 3, respectively).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the device of Hartman in view of Muller and incorporate a cooling unit into the delivery unit in order to provide cooling to the skin so as to lower the temperature of the epidermis during irradiation. This cooling would minimize or eliminate thermal damage to the epidermis in the irradiated region and surrounding tissues.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

U.S. Patent No. 6,436,127 B 1 to Anderson et al. teaches photodynamic apparatus and method of use for treating skin disorders such as psoriasis with ultraviolet light in the wavelength range of about 290 nm to 330 nm. Their treatment light has intensity greater than two minimal erythema dose (see Col. 3, lines 13-20).

U.S. Patent No. 6,017,360 to Chubb et al. teaches a phototherapeutic apparatus and method for irradiating skin of a patient with an ultraviolet light having an intensity of about 0.06 MED to 0.2 MED.

U.S. Patent No. Re. 36,634 to Ghaffari and U.S. Patent No. 5,595,568 to Anderson et al. teach apparatuses and methods for treating skin conditions, the

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apparatuses comprising; light sources, including UV light sources, for providing treatment energies; and cooling subsystems for cooling the skin during irradiation.

Njoo et al., "*The Development of Guidelines for the Treatment of Vitiligo*," Arch Dermatol, Vol. 135, Dec. 1999, disclose evidence-based guidelines from a scientific study for the treatment of vitiligo in children and in adults. They teach that a narrow-band UV-B light therapy is used for the treatment of localized vitiligo (see page 1518, Col. 2, paragraph 2). Table I describes the clinical types of vitiligo, such as localized vitiligo, generalized vitiligo, and vitiligo universalis. Table 3 discloses treatment scheme for vitiligo including the use of UV-B irradiation.

Rodewald et al., "*Dermatology Online Journal*," Vol. 7, No. 2001, disclose detailed studies for treating skin conditions such as vitiligo and localized psoriasis with UVB light (i.e., XeCl excimer laser).

Asawanonda et al., "*308-nm Excimer Laser for the Treatment of Psoriasis*" Arch Dermatol/ Vol. 136, May 2000, disclose a method for treating patients having skin disorder, the method comprising the steps of: providing a treatment light of 308 nm wavelength generated by a xenon chloride (XeCl) excimer laser; providing an optical fiber disposed between the excimer laser and the patients' skin to guide the treatment light (see page 620, column 1, paragraph 2, lines 2-4); and irradiating the laser light to a treatment area of the patient to treat skin disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-

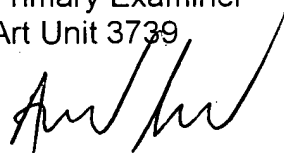
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4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ahmed M Farah
Primary Examiner
Art Unit 3739



June 12, 2005.